

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Toshihiro ITO et al.

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For: ENRICHED RICE OR ENRICHED WHEAT

Examiner: HANRAHAN,
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DECLARATION UNDER 37 CFR 1.132

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Sir:

I, Noboru SAKAGUCHI, residing in Mie-ken, Japan, hereby declares and states as follows:

1. That I am a co-inventor of the above-identified application, and thoroughly familiar with the contents of U.S. Application Serial No. 10/542,200 filed on July 15, 2005, entitled ENRICHED RICE OR ENRICHED WHEAT, its prosecution before the United States Patent and Trademark Office and the references cited therein.

2. I am a graduate of The University of Tokushima, Faculty of Engineering and received a master's degree in the year 1979, majoring in applied chemistry.

3. That I have been employed in Taiyo Kagaku Co., Ltd. in the year 1986 and have been assigned to the Research Laboratories.

4. I have been involved in the research and development of nutrition delivery system since 1999.

5. The following experiments were conducted by myself or under my direct supervision and control in order to verify that the present invention is clearly distinguishable from Misaki (U.S. Patent No. 4,765,996).

EXPERIMENTAL METHOD

In the following tests the raw materials described in Misaki were all commercially available products.

Preparation of Enriched Rice

Enriched Rice 1: The same procedures as in Example 5 of Misaki were carried out to give enriched rice (Enriched Rice 1).

Enriched Rice 2: The same procedures as in Example 5 of Misaki were carried out except that the aqueous suspension containing ferric pyrophosphate described in Example 5 of Misaki was changed to an emulsifying agent-coated iron salt composition A described in Example 1 of the present specification, to give enriched rice (Enriched Rice 2).

Enriched Rice 3: The same procedures as in Example 8 of the present specification were carried out using vitamins and minerals given in Example 5 of Misaki, so as to have final theoretical vitamin content and mineral content of nutrient enriched rice, to

give enriched rice (Enriched Rice 3). Here, the vitamins and the minerals were prepared in the same manner as in Example 3 of the present specification.

Enriched Rice 4: The same procedures as in Example 8 of the present specification were carried out using vitamins and minerals given in Example 5 of Misaki, so as to have final theoretical vitamin content and mineral content of nutrient enriched rice, except that the aqueous suspension containing ferric pyrophosphate described in Example 5 of Misaki was changed to an emulsifying agent-coated iron salt composition A described in Example 1 of the present specification, to give enriched rice (Enriched Rice 4). Here, the vitamins and the minerals were prepared in the same manner as in Example 3 of the present specification.

Test Methods

1. Residual Ratio Test of Vitamins and Minerals in Enriched Rice

The residual ratios of vitamins and minerals in the finally prepared enriched rice to the theoretical contents of vitamins and minerals were obtained from the amounts of vitamins and minerals used. The results are summarized in Table I. Here, the vitamin content and the mineral content were measured in according to the basis of Standard Methods of Analysis for Hygiene Chemists as described in Test Example 1 of the present specification.

Table I

Item	Residual Ratio (%) in Final Nutrition Enriched Rice			
	Enriched Rice 1	Enriched Rice 2	Enriched Rice 3	Enriched Rice 4
Vitamin B1	29.8	69.0	35.4	78.9
Vitamin B2	23.3	20.0	70.0	73.3
Vitamin B6	7.3	9.1	53.5	63.3
Vitamin E	47.5	54.7	69.0	80.7
Iron	50.5	62.4	86.0	91.6

Misaki involves a complicated production method, requiring a larger number of spray-coating steps, so that the residual ratios of vitamins and minerals are undesirably low. In addition, as is clear from the comparisons between Enriched Rice 1 and Enriched Rice 2 and between Enriched Rice 3 and Enriched Rice 4, the enriched rice prepared using the emulsifying agent-coated iron salt composition A described in Example 1 of the present specification also has an excellent residual ratio for vitamins.

2. Run-off Test of Vitamins and Minerals Upon Washing Rice

The percent loss of vitamins and minerals in a finally prepared enriched rice after washing was obtained. The results are summarized in Table II. Here, since a detailed method for run-off test of vitamins and minerals upon washing rice is not given in Example 5 of Misaki, the test was conducted according to the method described in Test Example 1 of the present specification. Also, the residual ratios were obtained on the basis of the found values for vitamins and minerals in the finally prepared enriched rice.

Table II

Item	Loss Percentage (%) by Washing Rice			
	Enriched Rice 1	Enriched Rice 2	Enriched Rice 3	Enriched Rice 4
Vitamin B1	2.31	1.30	4.27	3.87
Vitamin B2	4.91	3.78	4.90	4.18
Vitamin B6	4.67	4.54	4.23	1.64
Vitamin E	3.93	1.81	2.57	2.59
Iron	3.97	3.49	2.85	2.18

As is clear from the comparisons between Enriched Rice 1 and Enriched Rice 2 and between Enriched Rice 3 and Enriched Rice 4, it is found that the loss percentage is likely to be lowered by washing rice when the emulsifying agent-coated iron salt composition A described in Example 1 of the present specification is used.

3. Test for Residual Vitamins and Minerals upon Storage

The finally prepared enriched rice were stored at room temperature for one month in accordance with Test Example 2 of the present specification, and the residual ratios for the vitamins and the minerals contained in the enriched rice were obtained, and the results are summarized in Table III. Here, the residual ratios were obtained on the basis of the found values for the vitamins and the minerals of the finally prepared enriched rice.

Table III

Item	Residual Ratio (%) After One-Month Storage			
	Enriched Rice 1	Enriched Rice 2	Enriched Rice 3	Enriched Rice 4
Vitamin B1	51.6	84.3	56.1	85.4
Vitamin B2	85.9	94.3	88.6	93.7
Vitamin B6	61.7	79.8	59.3	81.4
Vitamin E	54.8	66.2	58.7	63.4
Iron	103.6	101.2	99.7	100.7

As is clear from the comparisons between Enriched Rice 1 and Enriched Rice 2 and between Enriched Rice 3 and Enriched Rice 4, the enriched rice using the emulsifying agent-coated iron salt composition A described in Example 1 of the present specification has excellent storage stability.

Statement Under 18 U.S.C. § 1001

The undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

Noboru Sakaguchi

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December 1, 2008

Date